REMARKS

This is a response to the Office Action of June 18, 2007.

Claims 2, 4, 7, 10, 14 ,15, 17, 19, 21, 23, 27, 28, 34, 39 - 46, 50, and 52 are pending. Claims 2, 4, 7, 10, 14, 15, 17, 19, 23, 27, 28, 34, 39, 40, 41, 44, 46, 50, and 52 are amended. Claims 16, 29, 32, 37, 47, and 53 - 64 are canceled.

These claims are canceled without prejudice to reclaiming the subject matter therein in a subsequent application.

Amendments to claims 2, 4, 7, 10, 14, 15, 17, 19, 23, 27, 28, 34, 39, 40, 41, 44, 46, 50 and 52 are supported in the originally filed specification. The aforementioned claims are amended to specify a stent, as opposed to a medical device. This amendment incorporates the features of claims 53-64 into the independent claims.

In addition, claims 2, 4, 7, 10, 14, 34, 39, 40, 44, and 50 recite the feature "supported by a surface of the stent" after the recitation of a "first layer." Claims 41 and 52 recites the feature "a coating supported by a surface of the stent." Although the exact phrase "supported by a surface of the stent" is not in the originally filed specification, applicant asserts that the phrase is supported by the Figures 2A – 2E, all of which illustrate various layers on top of a substrate. Further support can be found on page 8, lines 17-19 of the originally filed specification which states "[t]he coating comprises a coating applied on the surface of the stent." Moreover, the specification goes on to state, at page 8, lines 20-21, "[t]he coating according to embodiments of this invention optionally includes a polymer primer layer applied directly on the surface of the stent." Thus, the various embodiments of the invention include a layer applied directly to the stent surface, and those with an additional layer, referred to as a primer layer, between the stent surface and the "first layer." In either case, the support for the layers is provided by the surface of the stent, which is the substrate.

35 U.S.C. 112, first paragraph, requires the applicant to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, her or she was in possession of the invention." *Vas-Cath. Inc. v. Mahurkar*, 935 F.2d 1555, 1563 – 64 (Fed. Circ., 1991). An applicant can describe the invention "by such descriptive means as words, structures, figures, diagrams, formulas, etc." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir., 1997). In fact, drawings alone "may provide a 'written description' of an invention as required by § 112." *Vas-Cath*, 935 F.2d at 1565. However, to satisfy, the written description requirement, "the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue." *Crown Operations Int'l v. Krone*, 289 F.3d 1367, 1376 (Fed. Cir., 2002); see also, *Lockwood,* 107 F.3d at 1572. Thus, applicants assert that the combination of some of the embodiments illustrated in Figures 2A - 2E, along with the cited portions of the specification, support the feature "a first layer . . . supported by a surface of the stent," or the feature "a coating supported by a surface of the stent."

The above cited claims, as well as claims 15, 19, 28, and 46, also recite the feature "wherein the drug is light-sensitive, UV-sensitive, or both light-sensitive and UV-sensitive." This feature is supported by at least the disclosure at page 22, lines 10-12 of the originally filed specification.

Reconsideration and reexamination are respectfully requested in view of the foregoing claim amendments and the remarks presented below.

Interview Summary

Applicant's counsel greatly appreciates the courtesy extended by Examiner Fubara in granting an interview.

In the interview held on Tuesday, October 16, 2007 at 1:00 p.m. Eastern Daylight Time, Examiner Fubara, and applicant's counsel, Dr. Mark Lupkowski and Dr. Gloria Gusler, discussed the Examiner's rejection of claims 2, 7, 10, 14, 34, 39 - 41, 44, 50, 52 and 53 - 64 under 35 U.S.C. § 103(a) as being unpatentable over Kanikanti et al., United States Patent 5,900,425 ("Kanikanti") in view of Sinclair et al. United States Patent 5,760,118 ("Sinclair"), and further in view of Yan, United States Patent 6,240,616 ("Yan"). Applicant's representatives suggested some claim amendments and the Examiner also suggested claim amendments, both of which have been incorporated in the claims included in the Listing of Claims.

Claim Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 2, 7, 10, 14, 34, 39 - 41, 44, 50 and 52 under 35 U.S.C. § 103(a) as being unpatentable over Kanikanti in view of Sinclair.

Claims 2, 7, 10, 14, 34, 39 - 41, 44, 50, and 52 recite the feature "a stent." Sinclair includes reference to "medical applications involv[ing] internal use of the polymers, such as for sutures, prosthetic devices, and drug release matrices," (column 2, lines 50-52) in the "Background of the Invention," but there is no disclosure of "a stent." Similarly, Kanikanti does not include a disclosure of "medical device" or "stent." Therefore, applicants assert that all of the claim limitations have not been disclosed, and the difference between the applicant's invention, and the disclosure in the references, does not make a stent comprising a coating as claimed by applicant obvious. Thus, applicant asserts that claims 2, 7, 10, 14, 34, 39 - 41, 44, 50, and 52, as written, are patentably allowable over the combination of Kanikanti in view of Sinclair.

Applicant respectfully requests that the Examiner withdraw the obviousness rejection of claims 2, 7, 10, 14, 34, 39 - 41, 44, 50 and 52.

Although the Examiner's interpretation of the term "medical device," in her rejection of claims 2, 7, 10, 14, 34, 39 - 41, 44, 50, and 52 under 35 U.S.C. § 103(a) as being unpatentable over Kanikanti in view of Sinclair, is now moot with respect to the claims as written, applicant would like to respectfully disagree with the Examiner's interpretation of the term "medical device." In her Office Action of 18 June 2007, the Examiner has interpreted "medical device" to "read on any device that can be used medically including tablet or other in vitro reagents/product/composition comprising a core and a coating layer." Applicant respectfully disagrees with the Examiner's position, and applicant asserts that one of ordinary skill in the art would not interpret the term "medical device" to encompass a tablet containing a drug intended for oral ingestion.

The Examiner has rejected claims 15 - 17, 19, 21, 23, 27 - 29, 42, 43, and 45 - 47 under 35 U.S.C. § 103(a) as being unpatentable over Kanikanti in view of Sinclair.

Independent claims 15, 19, 28, and 46, as written, include the feature "a stent." As outlined above, Kanikanti and Sinclair do not disclose a stent. Thus, applicants assert that claims 15, 19, 28, and 46 are patentably allowable over Kanikanti and Sinclair. As the claims 16, 17, 21, 23, 27, 42, 43 and 46 depend from one of the independent claims 15, 19, 28 or 46, they are patentably allowable for at least the same reasons that the independent claims from which they depend are allowable.

Therefore, applicant respectfully requests that the Examiner withdraw the rejection of claims 15, 17, 19, 21, 23, 27 - 28, 42, 43, and 45 - 46 under 35 U.S.C. § 103(a). Rejection of claims 16, 29, and 47 is moot in light of their cancellation.

The Examiner has rejected claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Faour, United States Patent 6,352,721 ("Faour") in view of Verhoff et al., United States Patent 6,634,576 ("Verhoff"). The Examiner recites, as a motivation to combine the references, that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate carbon black as a diagnostic imaging agent as taught by Verhoff with the expectation of monitoring the release of the agent."

Applicants respectfully traverses the Examiner's rejection of claim 4 under 35 U.S.C. § 103(a) for at least the following reason.

Applicant asserts that the Examiner has not provided a proper motivation for combining the references. As noted above, the Examiner has asserted that Verhoff teaches that carbon black is a diagnostic agent. Applicant respectfully asserts that the Examiner has misinterpreted Verhoff. The only recitation of carbon black in the specification of Verhoff is in the following passage (column 54, line 64 to column 55, line 5):

> The invention may be applied to a very wide variety of solids which may be slurried with a wide range of liquids. Solids which may be milled include pharmaceutical agents such as drugs and diagnostic imaging contrast agents, iron oxide, talc, silica and other minerals like chalk, zinc oxide, boric oxide, borax, zinc borate, pigments, carbon black, various metals, solid organic compounds, e.g. terephthalic acid, and mixtures thereof, as well as solids previously mentioned.

Verhoff does not teach the use of carbon black as a diagnostic agent, as asserted by the Examiner. Verhoff teaches a process of milling a solid substrate in a milling chamber with two or more compositions of milling bodies such that fragments of one are retained with the solid substrate to make a co-mixture. Thus, in contrast to the assertion of the Examiner that Verhoff teaches the use of carbon black as a diagnostic agent, Verhoff merely lists carbon black as one of a "very wide variety of solids" to which "[t]he invention may be applied," or that is, a type of solid that can be milled using the process of Verhoff.

As the Examiner has provided no evidence that carbon black is a diagnostic imaging agent, the Examiner has not provided any motivation to combine the references. Therefore, applicant respectfully requests that the Examiner withdraw the rejection to claim 4.

The Examiner has rejected claims 2, 7, 10, 14, 34, 39 - 41, 44, 50, 52 and 53 - 64 under 35 U.S.C. § 103(a) as being unpatentable over Kanikanti in view of Sinclair and further in view of Yan, United States Patent 6,240,616 ("Yan").

Applicant would like to point out that claims 53 - 64 have been canceled. The limitation of "a stent" is recited in the independent claims as was discussed with the Examiner in the interview of October 16, 2007.

Applicant respectfully traverses the Examiner's rejection for at least the following reasons.

The Examiner asserts "it would have been obvious to one of ordinary skill in the art at the time the invention was made to deliver the combined composition of Kanikanti and Sinclair with a stent with the expectation of delivering active agent to the target site."

As discussed with the Examiner in the teleconference of October 16, 2007, applicants assert that the combination of Kanikanti in view of Sinclair, and further in view of Yan, is improper. Kanikanti discloses "an orally administrable solid, stable pharmaceutical preparation having high bioavailability and controlled, long lasting release . . . " (column 1, lines 28-30). Yan discloses "a method of manufacturing a medicated prosthesis such as a stent" which involves forming a porous material and filling the pores with active agents, but also may include application of a coating to the stent. Thus, Kanikanti discloses compositions for oral, or systemic, administration. Yan discloses compositions for local delivery, such as by a stent.

Local delivery allows for delivery of drug at a specific site which may be eventually absorbed into the blood stream. Oral delivery involves absorption of the drug from the gastrointestinal tract, with the drug generally going through the hepatic portal vein and then to the liver prior to distribution to the rest of the body via systemic circulation in the bloodstream. Some active agents are metabolized in the liver. Local delivery, such as by a stent, avoids or ameliorates the extent of metabolism of the drug by the liver. Local delivery also allows for higher concentrations to exist at the site where the drug is needed. In addition local delivery helps to avoid toxicity by limiting the amount of drug absorbed systemically. Moreover, the total dose of drug administered may be reduced as a larger fraction is delivered to the site of need, and this may also reduce toxicity. Thus, local drug delivery and oral drug delivery differ.

As the Examiner is combining a reference related to local delivery with a reference relating to medical prostheses, such as stents, applicant asserts that the Examiner's rejection under 35 U.S.C. § 103(a) is improper for the references cannot be combined. As noted in MPEP 2143.02 (VI):

> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Here the Examiner is suggesting modifying Kanikanti, a reference related to oral delivery, to obtain applicants invention, which involves local delivery, and thus the principle of operation would change.

Also, MPEP section 2143.01(V) states "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125

(Fed. Cir. 1984)." As outlined above, local and oral delivery are different, and therefore, the Examiner's modification of Kanikanti would make it unsatisfactory for it's intended purpose.

Furthermore, there is no overlap of the drugs of applicant's invention and those recited in Kanikanti or Sinclair. More particularly, the drugs of applicant's invention are not amenable to oral delivery. Thus, overlap of drugs does not provide a rationale for the combination of the references.

Therefore, claims 2, 7, 10, 14, 34, 39 - 41, 44, 50, and 52 are patentable over the combination of Kanikanti in view of Sinclair, and further in view of Yan. Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 103(a) of claims 2, 7, 10, 14, 34, 39 - 41, 44, 50, and 52. The rejection of claims 53 - 64 is moot in light of their cancellation.

The Examiner has rejected claims 15 - 17, 19, 21, 23, 27 - 29, 32, 37, 42, 43, and 45,-,47 under 35 U.S.C. § 103(a) as being unpatentable over Kanikanti in view of Sinclair and further in view of Yan.

Applicants respectfully traverse the Examiner's rejection for at least the following reasons.

The Examiner asserts "it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat a stent with the composition of Kanikanti and Sinclair in order to deliver the combined composition to the target site."

Applicant asserts that the Examiner's rejection under 35 U.S.C. § 103(a) is improper for the references cannot be combined for the reasons outlined above.

Therefore, claims 15, 17, 19, 21, 23, 27 - 28, 42, 43, and 45 - 46 are patentable over the combination of Kanikanti in view of Sinclair, and further in view of Yan. Applicant respectfully

requests that the Examiner withdraw the rejection under 35 U.S.C. § 103(a) of claims 15, 17, 19, 21, 23, 27 - 28, 42, 43, and 45 - 46. The rejection of claims 16, 29, 32, 37, 47, and 53 - 64 is moot in light of their cancellation.

Furthermore, at least claim 17 is independently patentable. The claim recites the specific active agents actinomycin D, paclitaxel, or vincristine. None of the three drugs are specifically listed in any of the three references cited above in the rejection of claim 17. Therefore, the proposed combination of references does not disclose all of the elements of this claim, and the choice of these three particular drugs based upon the disclosure of the references is not obvious. Thus, applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 103(a) of claim 17.

CONCLUSION

No new matter has been added, and all cancellations have been made merely to expedite prosecution of the application. Accordingly, applicant reserves the right to continue pursuing previously presented arguments in any divisional, continuation, or continuation-in-part applications. In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance.

If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned at (415) 954-0397.

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Respectfully submitted,

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 954-0397
Facsimile (415) 393-9887
ggusler@ssd.com

Gloria M. Gusler, Ph.D.
Attorney for Applicant
Reg. No. 50,282